Committee for Risk Assessment

RAC

Annex 2

Response to comments document (RCOM)

to the Opinion proposing harmonised classification and labelling at Community level of

Trisodium hexafluoroaluminate (Cryolite), synthetic and natural

ECHA/RAC/CLH-O-0000001052-90-02/A2
ECHA/RAC/CLH-O-0000001051-92-03/A2

Adopted

25 May 2010

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON CRYOLITES

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments that refer to several hazard classes are entered under each of the relevant categories/headings

Substance name / CAS number / EC number:

- Trisodium hexafluoroaluminate (Cryolite), synthetic / Purity: 95 % (85 – 97 %) / CAS no. 13775-53-6 / EC no. 237-410-6
- Trisodium hexafluoroaluminate (Cryolite), natural / Purity: 75 to 95 % / CAS no. 15096-52-3 / EC no. 239-148-8

General comments

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
17/12/2009	**Germany / Honeywell Specialty Chemicals Seelze GmbH**	Cryolite is a phase-in substance according to REACH. The substance has to be registered for the 2010 deadline. The registration dossier is in preparation by the lead registrant Solvay Fluor GmbH Germany in cooperation with the members of the REACH Fluoroaluminates Consortium. Currently we are evaluating the data and preparing the dossier and are not in a position to give comments on this classification proposal. When the dossier will be completed and evaluated then a classification proposal will be added. We request ECHA to delay a decision on the classification for Trisodium hexafluoroaluminate until the REACH dossier is accepted by the ECHA. This allows to decide on the classification to be based on the actual available data and its interpretation and It avoids confusion by	Noted.	Once RAC has received a C&L proposal, the proposal has to be processed without delays. Neither RAC nor ECHA can stop the procedure.

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		changing the classification more than once in a short period of time.		
17/12/2009	**Belgium / Eirik Nordheim / European Aluminium Association**	• Reproductive risk concerns are on the upswing in many regions of the world, owing in part to the increasing employment of women in traditionally male dominated industries. In recent years the aluminium industry has incorporated sustainability goals focused on increasing the proportion of women in smelters, a goal potentially jeopardized by this proposed reproductive hazard classification. Inevitably, allegations of harm to health will ensue, catalyzed by this new designation. The EHS, legal and human resources necessary to address such allegations will be sizeable. Well-intentioned employer practices and policies to protect women from cryolite exposures, driven in part by concerns generated by this new reproductive classification, could have unintended consequences for women (e.g. restricted job placement opportunities). For this reason it is necesssary to be carful in order to avoid overclassificatiob or classification based on questionable data. • It seems illogical to reclassify cryolite under GHS in advance of the completed REACH DNEL process. It is our understanding that the cryolite consortium is in the process of collating the existing literature base, which will better inform the risk assessment process.	Noted. The classification of chemicals is to reflect the type and severity of the intrinsic toxicological properties and hazards of a substance. It should not be confused with risk assessment which relates a given hazard to the actual exposure of humans to the substance displaying this hazard.	Once RAC has received a C&L proposal, the proposal has to be processed without delays. Neither RAC nor ECHA can stop the procedure.
16/12/2009	**Germany / Bernd**	Cryolite is a phase-in substance according	Noted.	Once RAC has received a C&L

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	Fleischer / Solvay Fluor GmbH, Hannover	to REACH. The substance has to be registered for the 2010 deadline. The registration dossier is in preparation by the lead registrant Solvay Fluor GmbH Germany in cooperation with the members of the REACH Fluoroaluminates Consortium. Currently we are not in a position to give comments on this classification proposal. When the dossier will be completed and evaluated then a classification proposal will be added. We recommend delaying a decision on the classification for Trisodium hexafluoroaluminate until the REACH dossier is accepted by the ECHA. This allows to decide on the classification based on the actual available data and its interpretation. It avoids confusion by changing the classification more than once in a short period of time.		proposal, the proposal has to be processed without delays. Neither RAC nor ECHA can stop the procedure.
17/12/2009	**Belgium / Eirik Nordheim / European Aluminium Association**	•The scientific basis of this recommendation is limited to animal toxicity studies, as no human epidemiologic data pertinent to cryolite, per se, are available. While general summaries of the cited EPA and US Federal Register studies are presented, the full study reports were not available to the rapporteur, nor to other stakeholders. It is requested that these original data/reports be made available for independent review and validation, prior to finalizing the proposed reproductive classification. Proceeding with classification without the	1. In most instances, toxicological assessment of chemicals is based on data obtained from animals. Valid human data is the exception rather than the rule. 2. In 2008, an attempt was made by the German CA to receive the full study reports from the US EPA/Cal EPA. However, the data were not provided. The German CA did not impeach the evaluation work of other international authorities reflecting the intrinsic hazards of cryolite. From synopsis of all data it is concluded that cryolite is classified as	We agree with the response. It is always advantageous to have the full reports, but in the absence of them we have to assess the available data, including work of other international authorities.

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
		benefit of such independent review is premature, and potentially undermines the integrity of the GHS process.	Repr. 2 H361d based on reported experimental data showing sufficient evidence to cause a strong suspicion of developmental toxicity in the absence of signs of marked maternal toxicity.	
14/12/2009	**United Kingdom / Christopher Bayliss / International Aluminium Institute**	NOTE: The analysis presented here represents a "worst case" hypothetical. For this analysis we chose the highest exposure job, in a manual setting potroom (older technology than modern smelters), with an assumption of no respiratory protection. Job modeled: Manual carbon setters, the job with the highest personal exposures in aluminium smelters Exposure surrogate for cryolite: particulate fluoride Exposure data (fluoride): arithmetic mean = 0.73mg/m3; 95th percentile = 2.1mg/m3. Calculated cryolite concentration: arithmetic mean = 1.3mg/m3; 95th percentile = 3.9mg/m3 • Cryolite concentration = concentrations of particulate fluoride multiplied by the ratio of the molecular weight of 3NaF AlF3 to F6 (210/114). Conservative Assumptions: • 10m3 volume of air inhaled over one working shift • No respiratory protection (NOTE: respiratory protection is universally used in the manual carbon setting job)	The presented analysis and the explanation of actual conditions and exposures in aluminium smelters were noted. No need for action. The German CA would like to point out that classification of a substance is to reflect the type and severity of the intrinsic hazard (i.e. the intrinsic toxic properties) of a substance. The hazard of a substance is the potential for that a substance to cause harm. In contrast, risk assessment relates a given hazard to the actual exposure of humans to the substance displaying this hazard. It is not intended to address risk assessment by preparing a proposal for classification and labelling.	We agree with the response from the German CA.

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		• Cryolite TWA arithmetic mean exposure = 1.3mg/m3 and 95th percentile exposure = 3.9mg/m3 • Body weight of 40kg (for a light female worker) • Inhaled cryolite is as bioavailable as ingested cryolite. Then the inhaled dose for the arithmetic mean exposure would be 13mg/day, which would equate to 0.33mg/kg bw/day or 0.8% of the oral NOAEL for developmental toxicity of 42mg/kg bw/day, and the inhaled dose for the 95th percentile exposure would be 39mg/day, which would equate to 0.98mg/kg bw/day or 2.3% of the oral NOAEL for developmental toxicity of 42mg/kg bw/day. Additional Safety Factors: The results above equate to an overall protection factor of 125 and 43, based on the arithmetic mean and 95th percentile exposures respectively, for the highest exposed smelter job, without considering respiratory protection. Respiratory protection would, of course always be used in manual setting operations, further increasing the protection factors. If further safety factors were applied to the recommended NOAEL for inter-species differences (animal data) and for individual susceptibility, the above protection factors would be reduced.		

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		 Adobe Acrobat Document		
14/12/2009	**United Kingdom / Christopher Bayliss / International Aluminium Institute**	ALUMINIUM INDUSTRY COMMENTS REGARDING REPRODUCTIVE TOXICITY SUMMARY (SECTION 5.9.5) ON PAGE 66 OF ANNEX VI: • The scientific basis of this recommendation is limited to animal toxicity studies, as no human epidemiologic data pertinent to cryolite, per se, are available. While general summaries of the cited EPA and US Federal Register studies are presented, the full study reports were not available to the rapporteur, nor to other stakeholders. It is requested that these original data/reports be made available for independent review and validation, prior to finalizing the proposed reproductive classification. Proceeding with classification without the benefit of such independent review is premature, and potentially undermines the integrity of the GHS process. • Due to the very high test dosing schemes used in the cited studies, the observed and reported effects (decreased pup weights during lactation; pathologic changes in pup organs) may be reasonable; however such dosage levels are much higher than occupational exposures found in the	In 2008, an attempt was made by the German CA to receive the full study reports from the US EPA/Cal EPA. However, the data were not provided. The German CA did not impeach the evaluation work of other international authorities reflecting the intrinsic hazards of cryolite. From synopsis of all data it is concluded that cryolite is classified as Repr.2 H361d based on reported experimental data demonstrating developmental toxicity in the absence of signs of marked maternal toxicity. It is correct that classification of a substance is distinct from risk assessment. Therefore, classification should not be confused with risk assessment which relates a given hazard to the actual exposure of humans to the substance displaying this hazard.	Once RAC has received a C&L proposal, the proposal has to be processed without delays. Neither RAC nor ECHA can stop the procedure. It is always advantageous to have the full reports, but in the absence of them we have to assess the available data, including work of other international authorities. We agree with the response.

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		typical modern day aluminium reduction plant. Hazard classification is distinct from risk assessment. In the workplace, the former inevitably leads to the latter to determine workplace risk control measures. Conservative modelling of typical potroom exposures for manual carbon setters, the job with the highest exposures in smelters, using both mean and 95th percentile data, yields, respectively, inhaled doses of cryolite of 0.8% and 2.3% of the oral NOAEL for developmental toxicity of 42 mg/kg bw/day. (see attached appendix for details)	The classification of a substance is to reflect the type(s) and severity(ies) of the intrinsic hazards of a substance. The hazard of a substance is the potential of a substance to cause harm. It depends on the intrinsic properties of a substance. In this connection hazard evaluation is the process by which information about the intrinsic properties of a substance is assessed to determine its potential to cause harm.	
		• The GHS classification, once finalised, will be imposed everywhere that the GHS is adopted, including North America, South America and Australia, regions with a strong aluminium industry presence. Once adopted it will be extremely difficult to challenge or change, even should new high quality scientific data become available in the future.	Noted, no need for action.	If new data challenging a classification becomes available, the classification can be reconsidered pending the submission of a new Annex VI C&L-proposal by a MS.
		• Perception of risk to the aluminium industry will be severely, and in our view, unnecessarily impacted and nearly impossible to 'overturn' once classified in this fashion.	Noted, no need for action.	
		• Reproductive risk concerns are on the upswing in many regions of the world, owing in part to the increasing	Noted.	Noted. However, one purpose with C&L is to provide information about the hazards a substance may constitute,

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		employment of women in traditionally male dominated industries. In recent years the aluminium industry has incorporated sustainability goals focused on increasing the proportion of women in smelters, a goal potentially jeopardized by this proposed reproductive hazard classification. Inevitably, allegations of harm to health will ensue, catalyzed by this new designation. The EHS, legal and human resources necessary to address such allegations will be sizeable. Well-intentioned employer practices and policies to protect women from cryolite exposures, driven in part by concerns generated by this new reproductive classification, could have unintended consequences for women (e.g. restricted job placement opportunities).		in order to enable workers to make sure that appropriate risk management measures have been implemented to make it possible for them to continue the work task.
		• In some regions of the world, such as Canada, cryolite does not currently carry a "toxic" designation. However, under this new classification, cryolite would almost certainly be considered a hazardous waste, which would complicate management, recycling and other commercial activities. This may also be true for other areas of the world.	Noted.	Noted, although this is not a factor to consider in deciding on appropriate C&L.
		NOTE: The analysis presented below represents a "worst case" hypothetical. For this analysis we chose the highest exposure job, in a manual setting potroom (older technology than modern smelters),	See our comment above.	Thanks for the information. However, the C&L should not be mixed with the risk/safety assessment of chemicals.

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		with an assumption of no respiratory protection. Job modeled: Manual carbon setters, the job with the highest personal exposures in aluminium smelters Exposure surrogate for cryolite: particulate fluoride Exposure data (fluoride): arithmetic mean = 0.73mg/m3; 95th percentile = 2.1mg/m3. Calculated cryolite concentration: arithmetic mean = 1.3mg/m3; 95th percentile = 3.9mg/m3 • Cryolite concentration = concentrations of particulate fluoride multiplied by the ratio of the molecular weight of 3NaF AlF3 to F6 (210/114). Conservative Assumptions: • 10m3 volume of air inhaled over one working shift • No respiratory protection (NOTE: respiratory protection is universally used in the manual carbon setting job) • Cryolite TWA arithmetic mean exposure = 1.3mg/m3 and 95th percentile exposure = 3.9mg/m3 • Body weight of 40kg (for a light female worker) • Inhaled cryolite is as bioavailable as ingested cryolite. Then the inhaled dose for the arithmetic mean exposure would be 13mg/day,		

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		which would equate to 0.33mg/kg bw/day or 0.8% of the oral NOAEL for developmental toxicity of 42mg/kg bw/day, and the inhaled dose for the 95th percentile exposure would be 39mg/day, which would equate to 0.98mg/kg bw/day or 2.3% of the oral NOAEL for developmental toxicity of 42mg/kg bw/day. Additional Safety Factors: Allowing for inter-species differences (animal data) and for individual susceptibility, an overall additional safety factor of 50 could be applied to the scenario above, which would equate to safety factors of 125 and 43, based on the arithmetic mean and 95th percentile exposures respectively, for the highest exposed smelter job, without considering respiratory protection.  Adobe Acrobat Document		

Toxicity to reproduction

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
18/12/2009	**Sweden/ Swedish Chemicals Agency**	P. 61 Developmental toxicity There are developmental studies available for rat, mouse and rabbit. The selected doses are very high but doses above the	The classification of cryolite is based on data from studies in rats and mice. There is sufficient evidence from these	Regarding developmental toxicity, we agree with the comment from Sweden. We are of the view that the maternal mortality in the two "positive"

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		level that causes > 10 % lethality in the dams should not be included in the evaluations of the reproductive toxic effects. In the Nemec 1991a study on mice bent limb bone is reported but at the same time increased mortality (how much is not stated) in the dams. It appears that the studies can be regarded as negative. The details of findings, enlarged hearts and pale liver and kidneys, in the fertility rat study are not reported nor are the decrease in fetal weight during lactation. Are the fetal weight decreased consecutively and in a dose dependant manner? A classification for lactation with R64 might be more appropriate than a classification for developmental toxicity. We cannot support the proposed classification as Repr. Cat. 3; R63.	studies of an adverse effect on development. Signs of developmental toxicity were observed at dose levels without any significant systemically toxic effects in parental animals or in the lactating dams. Because the primary data cannot be assessed and there remain some uncertainties on the full toxicological significance of the developmental effects observed in the pups and the dental fluorosis observed in the dams it was considered that classification as Repr. Cat. 3; R63/Repr. 2 H361d is the appropriate classification. There is no evidence from results of the one- and two-generation studies in animals that the observed toxic effects on offspring resulted from exposure via breast milk. In addition, there are no data demonstrating the presence of cryolite at potentially toxic levels in breast milk. Therefore data are insufficient to propose a classification of cryolite as R64/Lact. H362.	mouse developmental toxicity studies is too high to allow any meaningful conclusions on developmental toxicity to be drawn from these studies. As to the effects seen in the rat 2-generation study, we believe that the decreased pup weights observed in both generations is the only sign of developmental toxicity that can be assessed in relation to the classification criteria. The effect is however considered borderline, and the reporting is so poor that reversibility and degree of adversity can not be judged.
18/12/2009	**Ireland/ Health & Safety Authority**	The Irish CA is in agreement with the proposal to classify cryolite as Repr. Cat 3 R62 [Repr 2 H361d].	Noted.	The support from Ireland/Health and Safety Authority is noted. We, however, think that the evidence for developmental toxicity is too limited and the quality of the reporting too poor to warrant classification. See our response above.
17/12/2009	**Belgium / Eirik**	•The scientific basis of this	In 2008, an attempt was made by the	Once RAC has received a C&L

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	Nordheim / European Aluminium Association	recommendation is limited to animal toxicity studies, as no human epidemiologic data pertinent to cryolite, per se, are available. While general summaries of the cited EPA and US Federal Register studies are presented, the full study reports were not available to the rapporteur, nor to other stakeholders. It is requested that these original data/reports be made available for independent review and validation, prior to finalizing the proposed reproductive classification. Proceeding with classification without the benefit of such independent review is premature, and potentially undermines the integrity of the GHS process.	German CA to receive the full study reports from the US EPA / Cal EPA. However, the data were not provided. The German CA did not impeach the evaluation work of other international authorities reflecting the intrinsic hazards of cryolite. From synopsis of all data it is concluded that cryolite is classified as Repr. 2 H361d based on reported experimental data demonstrating developmental toxicity in the absence of signs of marked maternal toxicity.	proposal, the proposal has to be processed without delays. Neither RAC nor ECHA can stop the procedure. It is always advantageous to have the full reports, but in the absence of them we have to assess the available data, including work of other international authorities.
14/12/2009	**United Kingdom / Christopher Bayliss / International Aluminium Institute**	NOTE: The analysis presented here represents a "worst case" hypothetical. For this analysis we chose the highest exposure job, in a manual setting potroom (older technology than modern smelters), with an assumption of no respiratory protection. Job modeled: Manual carbon setters, the job with the highest personal exposures in aluminium smelters Exposure surrogate for cryolite: particulate fluoride Exposure data (fluoride): arithmetic mean = 0.73mg/m3; 95th percentile = 2.1mg/m3. Calculated cryolite concentration: arithmetic mean = 1.3mg/m3; 95th percentile = 3.9mg/m3	See our comment above.	See our response above.

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		• Cryolite concentration = concentrations of particulate fluoride multiplied by the ratio of the molecular weight of 3NaF AlF3 to F6 (210/114). Conservative Assumptions: • 10m3 volume of air inhaled over one working shift • No respiratory protection (NOTE: respiratory protection is universally used in the manual carbon setting job) • Cryolite TWA arithmetic mean exposure = 1.3mg/m3 and 95th percentile exposure = 3.9mg/m3 • Body weight of 40kg (for a light female worker) • Inhaled cryolite is as bioavailable as ingested cryolite. Then the inhaled dose for the arithmetic mean exposure would be 13mg/day, which would equate to 0.33mg/kg bw/day or 0.8% of the oral NOAEL for developmental toxicity of 42mg/kg bw/day, and the inhaled dose for the 95th percentile exposure would be 39mg/day, which would equate to 0.98mg/kg bw/day or 2.3% of the oral NOAEL for developmental toxicity of 42mg/kg bw/day. Additional Safety Factors: The results above equate to an overall protection factor of 125 and 43, based on the arithmetic mean and 95th percentile		

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		exposures respectively, for the highest exposed smelter job, without considering respiratory protection. Respiratory protection would, of course always be used in manual setting operations, further increasing the protection factors. If further safety factors were applied to the recommended NOAEL for inter-species differences (animal data) and for individual susceptibility, the above protection factors would be reduced.  Adobe Acrobat Document		
14/12/2009	**United Kingdom / Christopher Bayliss / International Aluminium Institute**	ALUMINIUM INDUSTRY COMMENTS REGARDING REPRODUCTIVE TOXICITY SUMMARY (SECTION 5.9.5) ON PAGE 66 OF ANNEX VI: • The scientific basis of this recommendation is limited to animal toxicity studies, as no human epidemiologic data pertinent to cryolite, per se, are available. While general summaries of the cited EPA and US Federal Register studies are presented, the full study reports were not available to the rapporteur, nor to other stakeholders. It is requested that these original data/reports be made available for independent review and validation, prior to finalizing the proposed reproductive classification.	See our comments above.	See our response above.

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		Proceeding with classification without the benefit of such independent review is premature, and potentially undermines the integrity of the GHS process. • Due to the very high test dosing schemes used in the cited studies, the observed and reported effects (decreased pup weights during lactation; pathologic changes in pup organs) may be reasonable; however such dosage levels are much higher than occupational exposures found in the typical modern day aluminium reduction plant. Hazard classification is distinct from risk assessment. In the workplace, the former inevitably leads to the latter to determine workplace risk control measures. Conservative modelling of typical potroom exposures for manual carbon setters, the job with the highest exposures in smelters, using both mean and 95th percentile data, yields, respectively, inhaled doses of cryolite of 0.8% and 2.3% of the oral NOAEL for developmental toxicity of 42 mg/kg bw/day. (see attached appendix for details) • The GHS classification, once finalised, will be imposed everywhere that the GHS is adopted, including North America, South America and Australia, regions with a strong aluminium industry presence. Once adopted it will be extremely difficult to challenge or change,	Noted, no need for action.	

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		even should new high quality scientific data become available in the future.		
		• Perception of risk to the aluminium industry will be severely, and in our view, unnecessarily impacted and nearly impossible to 'overturn' once classified in this fashion.	Noted, no need for action.	
		• Reproductive risk concerns are on the upswing in many regions of the world, owing in part to the increasing employment of women in traditionally male dominated industries. In recent years the aluminium industry has incorporated sustainability goals focused on increasing the proportion of women in smelters, a goal potentially jeopardized by this proposed reproductive hazard classification. Inevitably, allegations of harm to health will ensue, catalyzed by this new designation. The EHS, legal and human resources necessary to address such allegations will be sizeable. Well-intentioned employer practices and policies to protect women from cryolite exposures, driven in part by concerns generated by this new reproductive classification, could have unintended consequences for women (e.g. restricted job placement opportunities).	Noted.	
		• In some regions of the world, such as Canada, cryolite does not currently carry a "toxic" designation. However, under	Noted.	

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
		this new classification, cryolite would almost certainly be considered a hazardous waste, which would complicate management, recycling and other commercial activities. This may also be true for other areas of the world. NOTE: The analysis presented below represents a "worst case" hypothetical. For this analysis we chose the highest exposure job, in a manual setting potroom (older technology than modern smelters), with an assumption of no respiratory protection. Job modeled: Manual carbon setters, the job with the highest personal exposures in aluminium smelters Exposure surrogate for cryolite: particulate fluoride Exposure data (fluoride): arithmetic mean = 0.73mg/m3; 95th percentile = 2.1mg/m3. Calculated cryolite concentration: arithmetic mean = 1.3mg/m3; 95th percentile = 3.9mg/m3 • Cryolite concentration = concentrations of particulate fluoride multiplied by the ratio of the molecular weight of 3NaF AlF3 to F6 (210/114). Conservative Assumptions: • 10m3 volume of air inhaled over one working shift • No respiratory protection (NOTE:	See our comment above.	

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		respiratory protection is universally used in the manual carbon setting job) • Cryolite TWA arithmetic mean exposure = 1.3mg/m3 and 95th percentile exposure = 3.9mg/m3 • Body weight of 40kg (for a light female worker) • Inhaled cryolite is as bioavailable as ingested cryolite. Then the inhaled dose for the arithmetic mean exposure would be 13mg/day, which would equate to 0.33mg/kg bw/day or 0.8% of the oral NOAEL for developmental toxicity of 42mg/kg bw/day, and the inhaled dose for the 95th percentile exposure would be 39mg/day, which would equate to 0.98mg/kg bw/day or 2.3% of the oral NOAEL for developmental toxicity of 42mg/kg bw/day. Additional Safety Factors: Allowing for inter-species differences (animal data) and for individual susceptibility, an overall additional safety factor of 50 could be applied to the scenario above, which would equate to safety factors of 125 and 43, based on the arithmetic mean and 95th percentile exposures respectively, for the highest exposed smelter job, without considering respiratory protection.		

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17/12/2009	**Belgium / Eirik Nordheim / European Aluminium Association**	• Reproductive risk concerns are on the upswing in many regions of the world, owing in part to the increasing employment of women in traditionally male dominated industries. In recent years the aluminium industry has incorporated sustainability goals focused on increasing the proportion of women in smelters, a goal potentially jeopardized by this proposed reproductive hazard classification. Inevitably, allegations of harm to health will ensue, catalyzed by this new designation. The EHS, legal and human resources necessary to address such allegations will be sizeable. Well-intentioned employer practices and policies to protect women from cryolite exposures, driven in part by concerns generated by this new reproductive classification, could have unintended consequences for women (e.g. restricted job placement opportunities). For this reason it is necesssary to be carful in order to avoid overclassificatiob or classification based on questionable data. • It seems illogical to reclassify cryolite under GHS in advance of the completed REACH DNEL process. It is our understanding that the cryolite consortium is in the process of collating the existing literature base, which will better inform	Noted. The classification of chemicals is to reflect the type(s) and severity(ies) of the intrinsic hazards of a substance. It should not be confused with risk assessment which relates a given hazard to the actual exposure of humans to the substance	See our response above.

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		the risk assessment process.	displaying this hazard.	

Other hazards and endpoints

Date	Country/ Person/Organisation/ MSCA	Comment	Response	Rapporteur's comment
18/12/2009	**Sweden/ Swedish Chemicals Agency**	Acute toxic (P. 22-25.) and repeated dose toxicity (p.27) We agree with the proposed classification of the acute toxic and repeated dose effects. However, the classification as an eye irritant does not seem to be sufficiently underpinned by test results. One study is poorly reported also in a new study on AlF3 also lacks detailed information, but some conclusions can be made. AlF3 itself does not fulfils the criteria to be classified according to the criteria. Therefore, a comparison with AlF3 does not support a classification of cryolite.	Thank you for commenting. We know about the weak evidence of cryolite as an eye irritant. In our opinion the reported findings are not sufficient to exclude cryolite from suspicion causing eye irritation and require classification as Eye Irrit 2 H319 according CLP regulations. Therefore, final judgement for classification of cryolite as an eye irritant should be taken in RAC.	Regarding eye irritation, we agree with the comment from Sweden. As there is limited data, and in addition very poorly reported, we think that neither the animal data nor the human data are sufficient basis to support the classification proposal.
18/12/2009	**Ireland/ Health & Safety Authority**	The Irish CA is in agreement with the proposal to amend the existing Annex VI entry to delete classification as R22 [Acute Tox 4 H332]. With respect to the proposal to classify for eye irritation [R36 / Eye Irrit 2 H319]], the Irish CA is not in agreement. Our position is based on the limited data available and the precautionary nature of the proposal. The information presented on the	Thank you for commenting. See our answer to Sweden.	The support is noted. We agree with the declassification of acute oral toxicity. Regarding eye irritation, we agree with the comment from Ireland. See our response above.

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		potential cryolite induced eye irritation is very limited. Despite an outcome of 'no findings', the available Draize test is poorly reported and lacks any eye irritation grading data at 24, 48 and 72 hours. Additional information presented includes an EPA document stating that cryolite is a 'moderate eye irritant' and a safety data sheet indicating that aluminium fluoride is an eye irritant, however in both cases an evaluation cannot be made because the study reports were unavailable to Germany. Limited information is available from the epidemiological questionnaire; however in our opinion this information is difficult to interpret. In section 5.3.4, Germany states: "Overall, data regarding eye irritation are not fully consistent. However there is an indication that eye contact with cryolite may have an irritating effect". We agree that the data are inconsistent, but feel that the weight of evidence presented is precautionary rather than hazard based and therefore the data are not sufficient to support a classification for eye irritation [R36 / Eye Irrit 2 H319].		